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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,690

07/27/2005

Brid Delvin

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05/09/2006

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/527,690

Applicant(s)

DELVIN ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-15, 22, 23, 29, 38, 39 and 53-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 8-14, 29, 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 56-60 is/are rejected.
- 7) ☒ Claim(s) 22, 23 and 53-55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Pursuant to a second preliminary amendment, claims 15, 22, 23 have been amended, and claims 53-60 added. Claims 1-5, 8-15, 22, 23, 29, 38, 39, 53-60 are now pending

Applicants election of Group II with traverse (claims 15, 22, 23, 25, 26, 53-60) is acknowledged, as are the elected species, i.e., HIV is the disease to be treated, and the remaining elections are as follows:

- a) vaginal mucosa as the specific mucosa with which the formulation is contacted;
- b) UC-781 as the specific therapeutic agent that is present in the formulation;
- c) the elected "synthetic fluid" is that defined by claim 55;
- d) the composition is a synthetic fluid for vaginal use (as opposed to a "SCM");
- e & f) the synthetic fluid has two properties of the composition that is recited in claim 22, and those properties are pH and osmolarity

.

Applicants have traversed the restriction by arguing essentially that a skilled artisan practicing the invention of Group I would also be practicing the invention of Group II and vice versa.

However, this is not necessarily true. For example, a gynecologist might recommend prophylactic use of an antibiotic even if an infection is not present; this would apply to Group I but not Group II. Then there is the matter of administration of contraceptives,

abortifacients, fertility enhancing drugs, which would again apply to Group I but not Group II. And finally, there is the matter of vaginal lubricants or "sex enhancing" lubricants, which may contain one or more pharmacologically active compounds. Perhaps it is true that a thorough search for the Group I claims would mean that no further search would be required for the Group II claims; however, the converse is not true. The restriction is maintained.



Claim 56 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 recites the following chemical name, which is intended to refer to the structure of UC-781 that is provided on page 3 of the specification:

N-[4-chloro-3-(3-methyl-2-butenyloxy)phenyl]

However, this name is incomplete. The complete name is the following:

N-[4-chloro-3-(3-methyl-2-butenyloxy)phenyl]-2-methyl-3-furanocarbothioamide



The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of

section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 15 & 56-60 are rejected under 35 U.S.C. §103 as being unpatentable over Barnard (*Biochemistry* 36, 7786, 1997) in view of Borgman (USP 5,536,743) or DiPiano (US 2003/0143278) or Ahmad (US 2003/0091540).

Barnard discloses UC781. Also disclosed (last paragraph of the article) is that the compound would be useful in a vaginal microbiocidal formulation. Each of Borgman, DiPiano and Ahmad discloses microbiocidal formulations for vaginal use.

Thus, it would have been obvious to one of ordinary skill to incorporate the antiviral agent of Barnard into the vaginal formulations of the secondary references.



The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the

United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 15 is rejected under 35 U.S.C. §102(a, b or e) as being anticipated by Pauletti (US 2006/0002966) or Pauletti (US 2004/004307) or DiPiano (US 2003/0143278) or Ahmad (US 2003/0091540) or Bologna (US 2001/0031251) or Borgman (USP 5536743) or Okada (USP 4211769).

Each of Pauletti, DiPiano, Ahmad, Bologna, Borgman and Okada disclose the invention substantially as claimed.

The claim is anticipated.



✦

DAVID LUKTON, PH.D.
PRIMARY EXAMINER

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.